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10/783,640

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Raymond P. Silkaitis

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BRIAN R. WOODWORTH

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EXAMINER

SOREY, ROBERT A

ART UNIT

PAPER NUMBER

3626

MAIL DATE

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11/09/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/783,640	<b>Applicant(s)</b> SILKAITIS ET AL.	
	<b>Examiner</b> ROBERT SOREY	<b>Art Unit</b> 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/17/2009</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/17/2009 has been entered.

### ***Status of Claims***

2. In the amendment filed 09/17/2009, the following occurred: claims 1, 3, 4, 6, and 7, were amended; and claims 8-13 were added. Claims 1-13 are presented for examination.

### ***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. **Claims 1 and 6** are rejected under rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention recites a "caregiver" visually comparing the patient with the digital photo. In MPEP chapter 2105, it is stipulated that if the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then the claim is directed toward nonstatutory subject matter.

### ***Claim Rejections - 35 USC § 103***

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 1-7** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 7,154,397 to Zerhusen et al. in view of U.S. Patent Application Publication 2002/0038392 to De La Hueraga.

7. As per claim 1, Zerhusen et al. teaches a minimally distractive method for a caregiver to validate the right patient with visual confirmation between the patient and a display that is one of integrated with and adjacent to a user interface mounted on a medication pump housing in an intravenous medication management system, comprising:

--*storing a digital photo of a patient* (see: Zerhusen et al., column 1, lines 55-65, is met by "[p]atient data is stored in a memory of the point-of-care computer or in a main server"; and column 14 line 56 through column 15, line 3, is met by patient image or photo);

--*transmitting the digital photo* (Fig. 1, ele. 34; Fig. 2, ele. 34; and Fig. 129)(see: Zerhusen et al., column 1, lines 55-65, is met by "[a]ccess to all patient information is available to...any computer connected to the point-of-care computer through a communication network"; column 6, lines 36-41, is met by "signals can be transmitted between the network...and computer"; and column 27, lines 17-57); *and*

--placing the digital photo of the patient on the display such that the digital photo is located one of on and adjacent to the user interface (Fig. 3B, ele. 80; Fig. 4; and Fig. 49)(see: Zerhusen et al., column 14, lines 55-65, is met by “[a]n image or photo...of the patient is also illustratively displayed”; and column 15, lines 1-3, is met by “[a]n image or photo... of the patient is also illustratively displayed to confirm that the patient is the correct patient”);

--visually comparing of the patient with the digital photo of the patient on the display of the pump by the caregiver;

--whereby the caregiver only has to look away from the user interface mounted on the medical pump housing in one direction one time to complete the visual comparing step.

Zerhusen et al. teaches a display that “receive[s] information automatically from various monitors and medical devices such as vital signs monitor, bed therapy systems, IV pumps, and the like” (see: Zerhusen et al., column 1, lines 26-43) and that “[p]atient monitors 28, treatment devices 30, and therapy devices 32 are also coupled to computer 12”, computer 12 itself connected to display 24 taught by Zerhusen et al. (Fig. 1)(see: Zerhusen et al., column 6, lines 1-7), but fails to specifically point out that the display is part of or directly affixed to a *medical pump*; however, De La Huerga teaches a medication pump with a display (Fig. 17, ele. 100 and 123)(see: De La Huerga, paragraphs 145, 148-151, and 164). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Zerhusen et al. and De La Huerga. The well known elements described are merely a combination of

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old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

8. As per claim 2, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

*--transmitting the digital photo to the medical pump when delivery programming code associated with (Fig. 17)(see: De La Huerga, paragraph 145-152, is met by the pump receiving information, including delivery parameters) a medication order for the patient is transmitted to the medical pump (Fig. 126, especially ele. 1524; and Fig. 128, ele. 1548 and 1550)(see: Zerhusen et al., column 25 line 37 through column 26, line 39, is met by the message to the nurse indicating a medication delivery on his or her do-to list and the step of identifying the correct patient).*

9. As per claim 3, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

*--transmitting the digital photo to the medical pump when the medication pump has been associated with the patient by the medication management system (Fig. 128, ele. 1548 and 1550)(see: Zerhusen et al., column 2, lines 6-14, is met by identification signals being sent to and used by the medical management system devices to associate people and things with the system; and column 26, lines 23-39, is met by displaying "an image of the patient along with a display of the patient's name for viewing by the nurse").*

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10. As per claim 4, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

*--prompting the caregiver with the display to confirm on the user interface mounted on the medical pump housing that the patient matches the digital photo on the display (Fig. 128, ele. 1548, 1550, and 1552)(see: Zerhusen et al., column 14, line 56 through column 15, line 3; and column 26, lines 23-39, is met by “the nurse can verify that the patient being attended to is in fact the patient maintained in the hospital main database”).*

11. As per claim 5, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 4, and further teaches:

*--sending a confirmation that the patient matches the digital photo to a medication management unit (Fig. 128, ele. 1548 and 1550)(see: Zerhusen et al., column 14, line 56 through column 15, line 3; and column 26, lines 23-39, is met by “[i]f the correct patient is identified...then the nurse identification information is entered”) as a right patient match in a five rights check.*

12. As per claim 6, Zerhusen et al. teaches a medication management system for a caregiver to validate the right patient with visual confirmation between the patient and a display that is one of integrated with and adjacent to a user interface mounted on a medical pump housing in an intravenous medication management system, comprising:

*--a medication management unit having a processing unit and a storage medium coupled to the processing unit (Fig. 1 and Fig. 2)(see: Zerhusen et al., column 5, lines 26-35), the storage medium containing programming code executed by the processing*

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*unit to* (see: Zerhusen et al., at least column 5, lines 57-62, is met by “software” throughout):

--*store a digital photo of a patient* (see: Zerhusen et al., column 1, lines 55-65, is met by “[p]atient data is stored in a memory of the point-of-care computer or in a main server””; and column 14 line 56 through column 15, line 3, is met by patient image or photo), *and transmit the digital photo* (Fig. 1, ele. 34; Fig. 2, ele. 34; and Fig. 129)(see: Zerhusen et al., column 1, lines 55-65, is met by “[a]ccess to all patient information is available to...any computer connected to the point-of-care computer through a communication network”; column 6, lines 36-41, is met by “signals can be transmitted between the network...and computer”; and column 27, lines 17-57); *and*

--*electronic communication with the medication management unit, having a processor and a memory coupled to the processor, the memory containing programming code executed by the processor to receive the delivery programming code and the digital photo of the patient and to place the digital photo of the patient and the delivery programming code on the display such that the digital photo is located one of on and adjacent to the user interface* (Fig. 3B, ele. 80; Fig. 4; and Fig. 49)(see: Zerhusen et al., column 14, lines 55-65, is met by “[a]n image or photo...of the patient is also illustratively displayed”; and column 15, lines 1-3, is met by “[a]n image or photo...of the patient is also illustratively displayed to confirm that the patient is the correct patient”) so that a caregiver can visually compare the patient with the digital photo of the patient on the display of the pump to validate that the patient is the right patient to receive the medication intravenously from the pump by only looking away from the user



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interface mounted on the medical pump housing in one direction one time to complete the visual comparing step.

Zerhusen et al. teaches a display that “receive[s] information automatically from various monitors and medical devices such as vital signs monitor, bed therapy systems, IV pumps, and the like” (see: Zerhusen et al., column 1, lines 26-43) and that “[p]atient monitors 28, treatment devices 30, and therapy devices 32 are also coupled to computer 12”, computer 12 itself connected to display 24 taught by Zerhusen et al. (Fig. 1)(see: Zerhusen et al., column 6, lines 1-7), but fails to specifically point out that the display is part of or directly affixed to a *medical pump* and *transmit delivery programming code to the medical pump*; however, De La Huerga teaches a medication pump with a display (Fig. 17, ele. 100 and 123)(see: De La Huerga, paragraphs 145, 148-151, and 164) wherein the pump receives information, including delivery parameters (Fig. 17)(see: De La Huerga, paragraph 145-152). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Zerhusen et al. and De La Huerga. The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

13. As per claim 7, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 6, and further teaches:

*--wherein the medical pump is associated with the patient by the medical management system via the steps of machine reading a machine readable label on the*

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*medical pump and machine reading a machine readable label on one of the patient and a medication container* (see: De La Huerga, paragraph 30 and 41, is met by a controller to check machine readable patient wristband, IV bag information, and IV pump identification; and paragraph 30, 39, 103, 151, 157, 247, 249, and 275, is met by medicant bag check against pump and associated patient identification using machine readable labels).

14. As per claim 8, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--wherein the display is integrated with at least a portion of the user interface to define a touch screen and at least some parameters of the delivery programming code and the digital photo of the patient are displayed concurrently on the touch screen (Fig. 49 and Fig. 51)(see: Zerhusen et al., column 14, line 56 through column 15, line 33, is met by display including patient photo and medication delivery parameters shown in parallel, the display is a touch display).

15. As per claim 9, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 6, and further teaches:

--wherein the display is integrated with at least a portion of the user interface to define a touch screen and the processor executes the programming code such that at least some parameters of the delivery programming code and the digital photo of the patient are displayed concurrently on the touch screen (Fig. 1; Fig. 2; Fig. 49; Fig. 51; and Fig. 129)(see: Zerhusen et al., column 1, lines 55-65, is met by “[a]ccess to all patient information is available to...any computer connected to the point-of-care

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computer through a communication network; column 5, lines 54-67, is met by a computer providing controlled medication administration, the display being a touch screen that is used as a computer display; column 6, lines 36-41, is met by “signals can be transmitted between the network...and computer”; column 14, line 56 through column 15, line 33, is met by display including concurrently shown patient photo and medication delivery parameters, the display is a touch screen; and column 27, lines 17-57).

16. As per claim 10, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 6, and further teaches:

--wherein the right patient is further validated by an electronic comparison of patient identification information input by a machine reader from at least one of a machine readable indicator on the patient and a machine readable indicator on a medication container, and a patient identifier associated with an order for intravenous medication administration (Fig. 49 and Fig. 51)(see: Zerhusen et al., column 14, line 56 through column 15, line 33, is met by patient identifier being scanned, patient’s photo and medication administration information being displayed for confirmation, patient confirmation, and the medication being scanned for verification).

17. As per claim 11, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 9, and further teaches:

--wherein the touch screen is a dual function screen having a pump monitor screen portion and a web browser screen portion (Fig. 1, ele. 12 and 34; Fig. 2, ele. 12 and 34; and Fig. 129)(see: Zerhusen et al., column 1, lines 55-65, is met by “[a]ccess to

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all patient information is available to...any computer connected to the point-of-care computer through a communication network”; column 5, lines 54-67, is met by computer provides internet access and controlled medication administration; column 6, lines 36-41, is met by “signals can be transmitted between the network...and computer”; column 16, lines 40-47, is met by internet access; and column 27, lines 17-57; column 34, lines 12-16, is met by internet browser software; and column 35, lines 5-21, is met by internet access; and De La Hueraga, Fig. 17, ele. 100 and 123, is met by a medication pump with a display; paragraphs 145-152, and 164, is met by the pump receiving information, including delivery parameters).

18. As per claim 12, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 9, and further teaches:

--wherein the touch screen is at least approximately 12 centimeters by 12 centimeters (see: Zerhusen et al., Figs. 4-5B, is met by computer touch screen 24 which is at least approximately 12 centimeters by 12 centimeters; column 5, lines 54-67, is met by a computer providing controlled medication administration, the display being a touch screen that is used as a computer display; and column 14, line 56 through column 15, line 33, is met by the touch screen display).

19. As per claim 13, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 1, and further teaches:

--further comprising the step of validating the right patient by an electronic comparison of patient identification information input by a machine reader from at least one of a machine readable indicator on the patient and a machine readable indicator on

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a medication container, and a patient identifier associated with an order for intravenous medication administration (Fig. 49 and Fig. 51)(see: Zerhusen et al., column 14, line 56 through column 15, line 33, is met by patient identifier being scanned, patient's photo and medication administration information being displayed for confirmation, patient confirmation, and the medication being scanned for verification).

20. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 7,154,397 to Zerhusen et al. in view of U.S. Patent Application Publication 2002/0038392 to De La Huerga further in view of Examiner's Official Notice.

21. As per claim 12, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 9, and further teaches:

--wherein the touch screen is at least approximately 12 centimeters by 12 centimeters.

Zerhusen teaches a touch screen (see: Zerhusen et al., Figs. 4-5B, is met by computer touch screen 24; column 5, lines 54-67, is met by a computer providing controlled medication administration, the display being a touch screen that is used as a computer display; and column 14, line 56 through column 15, line 33, is met by the touch screen display), but fails to specifically teach that the touch screen is *at least approximately 12 centimeters by 12 centimeters*; however, the Examiner takes Official Notice that it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a touch screen of at least approximately 12 centimeters by 12 centimeters, such screens being well known and in use at the time; further, it would have been obvious to one of ordinary skill in the art at the time the invention was

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made to combine the teachings of Zerhusen et al, De La Huerga, and Official Notice.

The well known elements described are merely a combination of old elements, and in the combination, each element merely would have performed the same function as it did separately, and one of ordinary skill in the art would have recognized that the results of the combination were predictable.

22. **Claim 12** is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 7,154,397 to Zerhusen et al. in view of U.S. Patent Application Publication 2002/0038392 to De La Huerga further in view of the legal precedent set out in the MPEP.

23. As per claim 12, Zerhusen et al. teaches the invention substantially as claimed, see discussion of claim 9, and further teaches:

--wherein the touch screen is at least approximately 12 centimeters by 12 centimeters.

Zerhusen teaches a touch screen (see: Zerhusen et al., Figs. 4-5B, is met by computer touch screen 24; column 5, lines 54-67, is met by a computer providing controlled medication administration, the display being a touch screen that is used as a computer display; and column 14, line 56 through column 15, line 33, is met by the touch screen display), but fails to specifically teach that the touch screen is *at least approximately 12 centimeters by 12 centimeters*; however, the screen size does not affect the system or its functionality in a material way so as to distinguish over the prior art; therefore, the screen size, specifically the screen begin at least approximately 12 centimeters by 12 centimeters, is a matter of obvious design choice and the

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arrangement of specific elements in the prior art need not be exactly the same as those presented in the claims - section 2144.04 of the MPEP presents case law that sets legal precedent for supporting the rationale to reject based on design choice.

### ***Response to Arguments***

24. Applicant's arguments from the response filed on 09/17/2009 have been fully considered and will be addressed below in the order in which they appeared.

25. In the remarks, Applicant argues in substance that (1) the 35 U.S.C. 112, second paragraph, rejections should be withdrawn in view of a combination of argument and amendment.

The Examiner is in agreement and the rejections have been withdrawn. Specifically, Applicant's arguments, in view of the amendments, that were found persuasive are as follows: "The Examiner mistakenly thinks that this might mean the underlying source, object or binary code in a language such as C+, Java, or FORTRAN. However, the term delivery program code would be understood by one skilled in the art of electronic medical pumps for drug delivery to mean the parameters, limits or program values, for example and not by way of limitation the dose, rate, volume, and duration that one uses to program the pump fin controlled drug delivery", and "Examine is unclear as to what reads the machine readable labels and how this is done within the method recited. FIGS. 4 and 21 clearly show an input means or device 32, more particularly a handheld FDA, which has an input means 118 for reading machine readable indicia such as bar codes and RFID tags. Also described are means such as

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WID transmitters/receivers that “read” the machine readable labels when they are brought into proximity”.

26. In the remarks, Applicant argues in substance that (2) the 35 U.S.C. 103(a) rejections should be withdrawn because "1) one skilled in the art would not combine the cited references absent hindsight in view of the present application; and 2) the combination would still not meet all of the limitations of claims 1-7 as amended. One skilled in the art would not combine Zerhusen and De La Huerga because De La Huerga discloses other more reliable means for determining if the medication is for the right patient, and relying on visual right patient checking thus would be contrary to the teaching of De La Huerga add other prior art. A screen on the pump or medication dispenser in Zerhusen would either be redundant or not of sufficient size to be useful. At any rate, the limitation of only having to look in one direction away from a photo of the patient on the pump user intake once for a visual right patient determination is not shown or suggested by either reference. This allows the user to remain focused on programming the pump without looking around the room in several directions several times. Each time the caregiver looks away, there is an opportunity for errors or mishaps.”

The Examiner respectfully disagrees. Applicant’s arguments are not persuasive. In response to Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of



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ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Furthermore, the cited art fully meets all of Applicant's limitations. Zerhusen et al. teaches a main server connected to a point-of-care computer located at a patient's bed and bedside apparatus. The bed and bed apparatus is complete with all the tools a typical patient bed would be equipped with at the time of invention including IV medication stands and poles. In column 1, Zerhusen et al. teaches in the background of the invention that such setups include IV pumps. Zerhusen et al. further teaches storing and transmitting a photo of a patient to the bedside point-of-care computer, which is connected to the bedside apparatus and bed, and placing the digital photo on the display for confirmation purposes. Zerhusen et al. teaches the medical caregiver visually comparing the image or photo with the patient to confirm that the patient is the correct patient. Zerhusen et al. fails to specifically point out that the display is part of or directly affixed to a *medical pump*; however, De La Huerga was combined with Zerhusen et al. correctly as per MPEP 2141 (III) to meet the claimed invention and teach that it would have been obvious to one of ordinary skill in the art at the time the invention was made to either use Zerhusen et al.'s screen on De La Huerga's medication pump or place Zerhusen et al.'s screen in close proximity or "adjacent to" De La Huerga's medication pump with interface as already taught by Zerhusen et al. in column 1 and alluded to by the many mentions of IV medication stands and poles attached to the bed and bedside apparatus that Zerhusen et al.'s point-of-care computer

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controls. In fact, Applicant's validation method and system can be used with any medical device or simply alone at the patient's bedside, and there is nothing specific that ties the functionality of Applicant's validation method and system to a medication pump. Furthermore, in response to Applicant's argument that the placement allows the user to only have to look at the pump once and therefore can remain focused on programming the pump without looking around the room in several directions which reduces the opportunity for errors, this is a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. As described here, the screen is either integrated into or adjacent to the user interface mounted on the medication pump housing; therefore, Applicant's intended use that is considered with little weight as it does not does not result in a structural difference that distinguishes the claimed invention from the prior art. Finally, it is noted that as per the location of the display *such that the digital photo is located one of on and adjacent to the user interface mounted on a medical pump housing*, that the arrangement of specific elements in the prior art need not be exactly the same as those presented in the claims, and that section 2144.04 of the MPEP presents case law that sets legal precedent for supporting the rationale to reject based on design choice.

### **Conclusion**

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT SOREY whose telephone number is

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(571)270-3606. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM (EST).

28. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Gilligan can be reached on (571)272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

29. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. S./  
Examiner, Art Unit 3626  
3 November 2009

/C. Luke Gilligan/  
Supervisory Patent Examiner, Art Unit 3626